

Compendial Deferrals for USP38-NF33 1S

| Category | Monograph Title | Monograph Section | Scientific Liaison |
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| Revision | <3> TOPICAL AND TRANSDERMAL DRUG PRODUCTS - PRODUCT QUALITY TESTS PF 40(2) Pg. ONLINE | INTRODUCTION, PRODUCT QUALITY TESTS FOR TOPICALLY APPLIED TOPICAL AND TRANSDERMAL DRUG PRODUCTS, SPECIFIC TESTS FOR OPHTHALMIC DRUG PRODUCTS, SPECIFIC TESTS FOR TOPICALLY APPLIED SEMISOLID DRUG PRODUCTS, SPECIFIC TESTS FOR TRANSDERMAL DELIVERY SYSTEMS | Margareth Marques |
| New | <129> ANALYTICAL PROCEDURES FOR RECOMBINANT THERAPEUTIC MONOCLONAL ANTIBODIES PF 39(3) Pg. ONLINE | INTRODUCTION/Paragraph Text, INTRODUCTION/Size-Exclusion Chromatography, INTRODUCTION/Capillary SDS Electrophoresis (Reduced and Nonreduced), INTRODUCTION/Oligosaccharide Analysis—Analysis of N-Linked Oligosaccharides of Monoclonal Antibodies, INTRODUCTION/Oligosaccharide Analysis—Sialic acid Analysis | Anita Szajek |
| New | <165> PREKALLIKREIN ACTIVATOR PF 39(5) Pg. ONLINE | DEFINITION/Introduction, ASSAY/Prekallikrein Assay, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>, Standard Solutions | Kevin Carrick |
| New | <212> OLIGOSACCHARIDE ANALYSIS PF 40(3) Pg. ONLINE | Title, INTRODUCTION/Introduction, INTRODUCTION/ANALYTICAL PROCEDURES OVERVIEW, INTRODUCTION/SAMPLE PREPARATION, INTRODUCTION/SEPARATION AND IDENTIFICATION OF OLIGOSACCHARIDES, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>, ADDITIONAL REQUIREMENTS/APPENDIX I | Edith Chang |
| Revision | <232> ELEMENTAL IMPURITIES--LIMITS PF 40(2) Pg. ONLINE | INTRODUCTION, ROUTES OF EXPOSURE, DRUG PRODUCTS, DRUG SUBSTANCE AND EXCIPIENTS, ANALYTICAL TESTING | Kahkashan Zaidi |
| Revision | <233> ELEMENTAL IMPURITIES - PROCEDURES PF 40(2) Pg. ONLINE | INTRODUCTION, COMPENDIAL PROCEDURES 1 AND 2, REQUIREMENTS FOR ALTERNATE PROCEDURE VALIDATION, LIMIT PROCEDURES, QUANTITATIVE PROCEDURES, APPENDIX | Kahkashan Zaidi |
| New | <476> ORGANIC IMPURITIES IN DRUG SUBSTANCES AND DRUG PRODUCTS PF 40(3) Pg. ONLINE | Title, INTRODUCTION, IDENTIFICATION OF IMPURITIES IN DRUG SUBSTANCES AND DRUG PRODUCTS, ANALYTICAL PROCEDURES FOR IMPURITIES AND DEGRADATION PRODUCTS, REPORTING IMPURITIES AND DEGRADATION PRODUCTS, SETTING ACCEPTANCE CRITERIA FOR IMPURITIES AND DEGRADATION PRODUCTS, QUALIFICATION OF IMPURITIES AND DEGRADATION PRODUCTS | Antonio Hernandez-Cardoso |
| Revision | <751> METAL PARTICLES IN OPHTHALMIC OINTMENTS PF 39(5) Pg. ONLINE | Title, PROCEDURE- | William Brown |
| New | <800> HAZARDOUS DRUGS - HANDLING IN HEALTHCARE SETTINGS PF 40(3) Pg. ONLINE | Title, 1. INTRODUCTION, 2. LIST OF HDS, 3. TYPES OF EXPOSURE, 4. RESPONSIBILITIES OF PERSONNEL HANDLING HDS, 5. FACILITY DESIGN AND ENGINEERING CONTROLS, 6. PERSONAL PROTECTIVE EQUIPMENT, 7. HAZARD COMMUNICATION PROGRAM, 8. TRAINING FOR COMPOUNDING PERSONNEL, 9. RECEIVING, 10. TRANSPORTING, 11. DISPENSING HD DOSAGE FORMS NOT REQUIRING ALTERATION, 12. COMPOUNDING HD DOSAGE FORMS, 13. PROTECTION WHEN ADMINISTERING HDS, 14. CLEANING: DEACTIVATION, DECONTAMINATION, CLEANING, AND DISINFECTION, 15. SPILL CONTROL, 16. DISPOSAL, 17. ENVIRONMENTAL QUALITY AND CONTROL, 18. DOCUMENTATION, 19. MEDICAL | Jeanne Sun |

SURVEILLANCE, APPENDIX A: ACRONYMS AND DEFINITIONS, APPENDIX B: SUGGESTED STANDARD OPERATING PROCEDURES, APPENDIX C: TYPES OF BIOLOGICAL SAFETY CABINETS, APPENDIX D: BEST PRACTICES FOR HANDLING HDS, APPENDIX E: EXAMPLES FOR DESIGN OF HAZARDOUS DRUG COMPOUNDING AREAS, APPENDIX F: REQUIREMENTS FOR PERSONAL PROTECTIVE EQUIPMENT, APPENDIX G. BIBLIOGRAPHY

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| New | <1029> GOOD DOCUMENTATION GUIDELINES PF 40(3) Pg. ONLINE | Title, INTRODUCTION, PRINCIPLES OF GOOD DOCUMENTATION, DATA COLLECTION AND RECORDING, DIFFERENT TYPES OF GMP DOCUMENTS | Antonio Hernandez-Cardoso |
| Revision | <1065> ION CHROMATOGRAPHY PF 40(3) Pg. ONLINE | INTRODUCTION, APPARATUS, SAMPLE PREPARATION, PROCEDURE | Horacio Pappa |
| New | <1083> GOOD DISTRIBUTION PRACTICES PF 40(2) Pg. ONLINE | Title, INTRODUCTION, SCOPE | Desmond Hunt |
| New | <1083.1> QUALITY MANAGEMENT SYSTEM PF 40(2) Pg. ONLINE | Title, INTRODUCTION, MANAGEMENT RESPONSIBILITY, DOCUMENTATION, RESOURCES MANAGEMENT, OPERATIONS, COMPLAINTS, DEVIATIONS, RETURNS, RECALLS, COUNTERFEITS, AND REPROCESS AND REWORK PRODUCTS, MONITORING AND IMPROVEMENTS, VALIDATION, CHANGE CONTROL, REGULATORY AFFAIRS, APPENDIX | Desmond Hunt |
| New | <1083.2> ENVIRONMENTAL CONDITIONS MANAGEMENT PF 40(2) Pg. ONLINE | Title, INTRODUCTION, ENVIRONMENTAL CONTROLLED FACILITIES, EQUIPMENT, AND VEHICLES, PACKAGING FOR SHIPPING, PERFORMANCE QUALIFICATION, DATA MONITORING, SHORT-TERM EXCURSIONS, APPENDIX | Desmond Hunt |
| New | <1083.3> IMPORTATION AND EXPORTATION MANAGEMENT PF 40(2) Pg. ONLINE | Title, INTRODUCTION, GENERAL REQUIREMENTS, MATERIAL OR PRODUCT KNOWLEDGE, GLOBAL SOURCING KNOWLEDGE, APPENDIX | Desmond Hunt |
| New | <1083.4> SUPPLY CHAIN INTEGRITY AND SECURITY PF 40(2) Pg. ONLINE | Title, INTRODUCTION, SUPPLY CHAIN INTEGRITY, SUPPLY CHAIN SECURITY, APPENDIX | Desmond Hunt |
| Revision | <1086> IMPURITIES IN DRUG SUBSTANCES AND DRUG PRODUCTS PF 40(3) Pg. ONLINE | INTRODUCTION, DRUG SUBSTANCE, DRUG PRODUCT, DEFINITIONS, INTRODUCTION, APPENDIX 1: DEFINITIONS, APPENDIX 2: ADDITIONAL SOURCES OF INFORMATION AND GUIDANCE | Antonio Hernandez-Cardoso |
| New | <1168> COMPOUNDING FOR INVESTIGATIONAL STUDIES PF 39(5) Pg. ONLINE | I. INTRODUCTION, II. REGULATORY ENVIRONMENT AND GUIDANCE, III. FACILITIES, IV. EQUIPMENT, V. PERSONNEL, VI. MATERIALS MANAGEMENT-PREPARATION, VII. MATERIALS MANAGEMENT-FINISHED PREPARATION, VIII. COMPOUNDING, IX. PACKAGING, LABELING, AND LABELS, X. QUALITY ASSURANCE PROGRAM MANAGEMENT, XI. STABILITY, STORAGE, AND DISTRIBUTION, XII. PROCEDURES AND DOSAGE FORMS, XIII. MISCELLANEOUS, XIV. CONCLUSIONS | Rick Schnatz |
| New | <1200> REQUIREMENTS FOR COMPENDIAL VALIDATION PF 39(6) Pg. ONLINE | Title, Introduction, GENERAL CONSIDERATIONS, TYPE 1 STUDY: PRECISION-ACCURACY AND RANGE, TYPE 2 STUDY: SPECIFICITY, TYPE 3 STUDY: ACCURACY, TYPE 4 STUDY: PRECISION, TYPE 5 STUDY: DETECTABILITY | Horacio Pappa |
| New | <1228> DEPYROGENATION PF 40(2) Pg. ONLINE | INTRODUCTION, INPUT CONTROL, PROCESS CONTROL, DIRECT CONTROL, SELECTION OF AN APPROPRIATE DEPYROGENATION METHOD, VALIDATION OF A DEPYROGENATION METHOD, ROUTINE PROCESS CONTROL | Radhakrishna Tirumalai |

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| New | < 1228.1> DRY HEAT DEPYROGENATION PF 40(3) Pg. ONLINE | INTRODUCTION, TECHNOLOGIES USED FOR DEPYROGENATION BY DRY HEAT, DRY HEAT DEPYROGENATION FUNDAMENTALS, DEPYROGENATION PROCESS CONTROL, VALIDATION, ROUTINE PROCESS CONTROL, REFERENCES | Radhakrishna Tirumalai |
| New | < 1602> SPACERS AND VALVED HOLDING CHAMBERS USED WITH INHALATION AEROSOLS PF 40(1) Pg. ONLINE | Title, INTRODUCTION, MEASUREMENT OF APSD AND SUBFRACTIONS WITH NO DELAY BETWEEN INHALER ACTUATION AND SAMPLING ONSET, MEASUREMENT OF APSD AND SUBFRACTIONS WITH DELAY BETWEEN INHALER ACTUATION AND SAMPLING ONSET, TOTAL MASS OF DRUG DELIVERED FROM A SPACER/VHC WHILE SIMULATING PATIENT TIDAL BREATHING, TOTAL MASS OF DRUG DELIVERED FROM A SPACER/VHC WITH FACEMASK WHILE SIMULATING PATIENT TIDAL BREATHING | Kahkashan Zaidi |
| New | 5-HYDROXY-L-TRYPTOPHAN PF 40(2) Pg. ONLINE | Title, Chemical Info/Chemical Structure, Chemical Info/C11H12N2O3, Chemical Info/220.23, Chemical Info/(S)-2-Amino-3-(5-hydroxy-1H-indol-3-yl)propanoic acid, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Chloride and Sulfate, Sulfate <221>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 5-Hydroxy-l-tryptophan RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP l-Tryptophan RS | Huy Dinh |
| Revision | ACETAMINOPHEN SUPPOSITORIES PF 39(3) Pg. ONLINE | IMPURITIES/4-Aminophenol in Acetaminophen-Containing Drug Products <227> | Clydewyn Anthony |
| New | (R)-(-)-ALPHA-PHELLANDRENE PF 39(4) Pg. ONLINE | Reagent Specification, (R)-(-)-α-Phellandrene | Hong Wang |
| New | (+)-ALPHA-PINENE PF 39(4) Pg. ONLINE | Reagent Specification, (+)-α-Pinene | Hong Wang |
| Revision | AMILORIDE HYDROCHLORIDE PF 40(1) Pg. ONLINE | IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amiloride Related Compound A RS | Sujatha Ramakrishna |
| Revision | AMINO BENZOATE POTASSIUM PF 39(1) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure | Hillary Cai |
| Revision | AMINO BENZOATE SODIUM PF 39(1) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure | Hillary Cai |
| New | AMINOLEVULINIC ACID HYDROCHLORIDE PF 40(2) Pg. ONLINE | Chemical Info/C5H9NO3·HCl, Chemical Info/167.59, Chemical Info/5-Aminolevulinic acid hydrochloride; , Chemical Info/5-Amino-4-oxopentanoic acid hydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption, <197K> or <197A>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Loss On Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aminolevulinic Acid Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aminolevulinic Acid Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Aminolevulinic Acid Related Compound B RS | Feiwen Mao |

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| New | AMIODARONE HYDROCHLORIDE INJECTION PF 39(6) Pg. ONLINE | <p>Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Iodide, OTHER COMPONENTS/Content of Benzyl Alcohol (if present), SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amiodarone Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amiodarone Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amiodarone Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS</p> | Sujatha Ramakrishna |
| New | AMLODIPINE AND VALSARTAN TABLETS PF 40(2) Pg. ONLINE | <p>Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Besylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amlodipine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Valsartan RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Valsartan Related Compound B RS</p> | Sujatha Ramakrishna |
| Revision | ANETHOLE PF 40(1) Pg. ONLINE | <p>DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B. Chromatographic Identity, ASSAY/Assay for trans-Anethole, IMPURITIES/Limit of cis-Anethole, p-Anisaldehyde, and Other Volatile Impurities, IMPURITIES/Aldehydes and Ketones, SPECIFIC TESTS/Congearing Temperature <651>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11></p> | Galina Holloway |
| New | ASTRAGALUS ROOT PF 40(3) Pg. ONLINE | <p>Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Isoflavonoids and Saponins, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 1 <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method 1 <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astragaloside IV RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astragalus Root Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calycosin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calycosin 7-O-β-D-Glucopyranoside RS,</p> | Anton Bzhelyansky |

ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daidzein RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daidzin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Formononetin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ononin RS

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Isoflavonoids and Saponins, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Residue on Ignition <281>, SPECIFIC TESTS/Botanical Extracts, Residual Solvents <565>, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astragaloside IV RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astragalus Root Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calycosin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calycosin 7-O- β -d-Glucopyranoside RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daidzein RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daidzin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Formononetin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ononin RS

New ASTRAGALUS ROOT DRY EXTRACT PF 40(3) Pg. ONLINE

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Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of Isoflavonoids and Saponins, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 1 <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method 1 <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astragaloside IV RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Astragalus Root Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calycosin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calycosin 7-O- β -d-Glucopyranoside RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daidzein RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daidzin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Formononetin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ononin RS

New ASTRAGALUS ROOT POWDER PF 40(3) Pg. ONLINE

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| New | ATAZANAVIR SULFATE PF 40(2) Pg. ONLINE | Title, Chemical Info/Chemical Structure, Chemical Info/C38H52N6O7 · H2SO4, Chemical Info/802.93, Chemical Info/2,5,6,10,13-Pentaazatetradecanedioic acid, 3-12-bis(1,1-dimethylethyl)-8-hydroxy-4,11-dioxo-9-(phenylmethyl)-6-[[4-(2-pyridinyl)phenyl]methyl]-, dimethyl ester, (3S,8S,9S,12S)-, sulfate (1:1) (salt);, Chemical Info/Dimethyl (3S,8S,9S,12S)-9-benzyl-3,12,di-tert-butyl-8-hydroxy-4,11-dioxo-6-(p-2-pyridylbenzyl)-2,5,6,10,13-pentaazatetradecanedioate, sulfate (1:1) (salt), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General, Sulfate <191>, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Atazanavir Related Compound A, SPECIFIC TESTS/Water Determination <921>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atazanavir Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atazanavir Sulfate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atazanavir System Suitability Mixture RS | Shankari Shivaprasad |
| New | ATAZANAVIR CAPSULES PF 40(2) Pg. ONLINE | Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atazanavir Sulfate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Atazanavir System Suitability Mixture RS | Shankari Shivaprasad |
| Revision | ATROPINE SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Heather Joyce |
| Revision | BACITRACIN OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage | Ahalya Wise |
| Revision | BACITRACIN ZINC AND POLYMYXIN B SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | ASSAY/Bacitracin, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage | Ahalya Wise |
| Revision | BENZOCAINE OINTMENT PF 40(2) Pg. ONLINE | IDENTIFICATION/A. Ointments Having Water-Soluble Bases, IDENTIFICATION/B. Ointments Having Water-Insoluble Bases, IDENTIFICATION/B., ASSAY/Ointments Having Water-Soluble Bases, ASSAY/Ointments Having Water-Insoluble Bases, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11> | Domenick Vicchio |
| Revision | BENZYL BENZOATE PF 39(6) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of Aldehydes, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP | Shankari Shivaprasad |

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| | | Benzaldehyde RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzoic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzyl Alcohol RS | |
| New | BETA-PINENE PF 39(4) Pg. ONLINE | Reagent Specification, β-Pinene | Hong Wang |
| Revision | BUPROPION HYDROCHLORIDE PF 39(4) Pg. ONLINE | ASSAY/Procedure, IMPURITIES/Limit of m-Chlorobenzoic Acid, IMPURITIES/Limit of 3-Chlorobenzoic Acid, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupropion Hydrochloride Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bupropion Hydrochloride Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 3-Chlorobenzoic Acid RS | Heather Joyce |
| Revision | BUTYLATED HYDROXYTOLUENE PF 40(2) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Congeaing Temperature <651> | Galina Holloway |
| New | CALCIPOTRIENE PF 39(4) Pg. ONLINE | Chemical Info/Chemical Structure, Chemical Info/C27H40O3, Chemical Info/412.60, Chemical Info/9,10-Secochola-5,7,10(19),22-tetraene-1,3,24-triol, 24-cyclopropyl-, (1α,3β,5Z,7E,22E,24S)-, Chemical Info/(5Z,7E,22E,24S)-24-Cyclopropyl-9,10-secochola-5,7,10(19),22-tetraene-1α,3β,24-triol, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities by HPLC, IMPURITIES/Organic Impurities by TLC, SPECIFIC TESTS/Loss on Drying, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcipotriene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcipotriene Related Compound C RS | Feiwen Mao |
| New | CALCIPOTRIENE OINTMENT PF 39(4) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Ultraviolet Absorption <197U>, ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill <755>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcipotriene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Calcipotriene Related Compound C RS | Feiwen Mao |
| Revision | CETOSTEARYL ALCOHOL PF 40(2) Pg. ONLINE | Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Related Fatty Alcohols, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Arachidyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lauryl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Linolenyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Myristyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleyl Alcohol RS | Galina Holloway |
| Revision | CETYL ALCOHOL PF 40(1) Pg. ONLINE | Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. | Galina |

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| | | Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Related Fatty Alcohols, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lauryl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Myristyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleyl Alcohol RS | Holloway |
| Revision | CHLORAMPHENICOL OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | ASSAY/Procedure, SPECIFIC TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Revision | CHLORAMPHENICOL AND POLYMYXIN B SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | ASSAY/Chloramphenicol, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Revision | CHLORDIAZEPOXIDE HYDROCHLORIDE FOR INJECTION PF 40(2) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, SPECIFIC TESTS/Other Requirements | Heather Joyce |
| Revision | CHLORTETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Revision | CHOLESTEROL PF 39(3) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197A> or <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11> | Galina Holloway |
| New | CHONDROITIN SULFATE SODIUM, SHARK PF 38(6) Pg. ONLINE | Chemical Info/Chondroitin, hydrogen sulfate, sodium salt, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Identification Tests—General, Sodium <191>, IDENTIFICATION/C. Specific Disaccharides, IDENTIFICATION/D. Specific Rotation, COMPOSITION/Content of Chondroitin Sulfate Sodium, COMPOSITION/Disaccharide Composition, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Chloride and Sulfate, Sulfate <221>, IMPURITIES/Electrophoretic Purity, IMPURITIES/Limit of Protein, CONTAMINANTS/Elemental Impurities—Procedures <233>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Clarity and Color of Solution, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chondroitin Sulfate Sodium, Shark RS | Huy Dinh |
| Revision | CICLOPIROX OLAMINE PF 40(3) Pg. ONLINE | IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ciclopirox Related Compound C RS | Shankari Shivaprasad |
| Revision | CIPROFLOXACIN PF 40(3) Pg. ONLINE | ASSAY/Procedure, IMPURITIES/Procedure 1: Limit of Fluoroquinolonic Acid, | Shankari |

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| | | IMPURITIES/Procedure 2, IMPURITIES/Organic Impurities | Shivaprasad |
| Revision | CIPROFLOXACIN HYDROCHLORIDE PF 40(3) Pg. ONLINE | ASSAY/Procedure, IMPURITIES/Procedure 1: Limit of Fluoroquinolonic Acid, IMPURITIES/Procedure 2, IMPURITIES/Organic Impurities | Shankari Shivaprasad |
| Revision | CIPROFLOXACIN OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Shankari Shivaprasad |
| Revision | CLOTRIMAZOLE PF 39(6) Pg. ONLINE | ASSAY/Procedure, IMPURITIES/Organic Impurities | Shankari Shivaprasad |
| Revision | CLOTRIMAZOLE CREAM PF 40(3) Pg. ONLINE | IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imidazole RS | Shankari Shivaprasad |
| Revision | CLOTRIMAZOLE TOPICAL SOLUTION PF 40(3) Pg. ONLINE | IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imidazole RS | Shankari Shivaprasad |
| Revision | CODEINE PHOSPHATE PF 38(6) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Morphine, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Codeine System Suitability Mixture C11 RS | Hillary Cai |
| Revision | CROMOLYN SODIUM PF 40(1) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Oxalate, SPECIFIC TESTS/Acidity or Alkalinity, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound B RS | Ravi Ravichandran |
| Revision | CROMOLYN SODIUM OPHTHALMIC SOLUTION PF 40(1) Pg. ONLINE | IDENTIFICATION/A., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cromolyn Related Compound B RS | Domenick Vicchio |
| Revision | DESCRIPTION AND SOLUBILITY PF 39(2) Pg. ONLINE | Desloratadine, Topotecan Hydrochloride, Glyceryl Monocaprylate, Glyceryl Monocaprylocaprate, Calcipotriene, Eucalyptus Oil, Imatinib Mesylate, Polyethylene Glycol, Polyethylene Glycol 3350, Aminolevulinic Acid Hydrochloride, Atazanavir Sulfate, Levocetirizine Dihydrochloride, Rosuvastatin Calcium, Tolterodine Tartrate | Domenick Vicchio |
| New | DESLORATADINE PF 39(2) Pg. ONLINE | Chemical Info/Chemical Structure, Chemical Info/C19H19CIN2, Chemical Info/310.82, Chemical Info/Benzo[5,6]cyclohepta[1,2-b]pyridine, 8-chloro-6,11-dihydro-11-(4-piperidinylidene)-, 5H-, ; Chemical Info/8-Chloro-6,11-dihydro-11-(piperidin-4-ylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Desloratadine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards | Domenick Vicchio |

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| | | <11>/USP Desloratadine Related Compound A RS | |
| Revision | DEXAMETHASONE TABLETS PF 39(5) Pg. ONLINE | IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A. Infrared Absorption <197>, IDENTIFICATION/B., IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methylprednisolone RS | Domenick Vicchio |
| Revision | DEXAMETHASONE SODIUM PHOSPHATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Domenick Vicchio |
| New | DEXTRAN OF WEIGHT-AVERAGE MOLECULAR WEIGHT 3,500,000 G/MOL PF 40(1) Pg. ONLINE | Dextran, Weight-Average Molecular Weight 3,500,000 g/mol | Hong Wang |
| Revision | DOXORUBICIN HYDROCHLORIDE PF 40(3) Pg. ONLINE | IDENTIFICATION/A., IDENTIFICATION/B. Infrared Absorption <197K>, IDENTIFICATION/C. Identification Tests-General, Chloride <191>, ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2: Limit of Solvent Residues (as Acetone and Alcohol), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Acetone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daunorubicin Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daunorubicinone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxorubicinone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epirubicin Hydrochloride RS | Ahalya Wise |
| Revision | DOXORUBICIN HYDROCHLORIDE INJECTION PF 40(3) Pg. ONLINE | IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Daunorubicinone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Doxorubicinone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epirubicin Hydrochloride RS | Ahalya Wise |
| Revision | ECONAZOLE NITRATE PF 40(2) Pg. ONLINE | 24169-02-6Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Econazole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Econazole Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Econazole Related Compound C RS | Shankari Shivaprasad |
| Revision | ENOXAPARIN SODIUM PF 37(1) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/B. 13C NMR Spectrum, IDENTIFICATION/C., IDENTIFICATION/D., IDENTIFICATION/E., IMPURITIES/Heavy Metals, Method I <231>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Bacterial Endotoxins Test <85> | Anita Szajek |
| Revision | ENOXAPARIN SODIUM INJECTION PF 37(1) Pg. ONLINE | IDENTIFICATION/C. Identification Tests—General Sodium<191> Spectrophotometry and Light-Scattering <851>, OTHER COMPONENTS/Benzyl Alcohol Content (if Present), SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Anti-Factor IIa Activity | Anita Szajek |

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| New | ENROFLOXACIN COMPOUNDED ORAL SUSPENSION, VETERINARY PF 39(4) Pg. ONLINE | DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Enrofloxacin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Enrofloxacin Related Compound Mixture RS | Jeanne Sun |
| New | 15-EPICARBOPROST PF 40(3) Pg. ONLINE | 15-Epicarboprost | Ravi Ravichandran |
| Revision | EPITETRACYCLINE HYDROCHLORIDE PF 40(1) Pg. ONLINE | IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Limit of 4-Epianhydrotetracycline, SPECIFIC TESTS/4-Epianhydrotetracycline <226>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anhydrotetracycline Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Epianhydrotetracycline Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epitetracycline Hydrochloride RS | Ahalya Wise |
| Revision | ERYTHROMYCIN OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage | Ahalya Wise |
| New | EUCALYPTUS OIL PF 39(4) Pg. ONLINE | Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Content of Aroma Substances, IMPURITIES/Test for Aldehyde, SPECIFIC TESTS/Specific Gravity <841>, SPECIFIC TESTS/Refractive Index <831>, SPECIFIC TESTS/Optical Rotation <781>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/US Reference Standards <11>/USP Camphor RS, ADDITIONAL REQUIREMENTS/US Reference Standards <11>/USP Eucalyptol RS, ADDITIONAL REQUIREMENTS/US Reference Standards <11>/USP Eucalyptus Oil RS | Hong Wang |
| New | FENUGREEK SEED PF 39(6) Pg. ONLINE | Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography-Amino Acid Profile, IDENTIFICATION/B. Thin-Layer Chromatography-Steroidal Saponins Profile, COMPOSITION/Content of 4-Hydroxyisoleucine, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Presence of Trigonelline, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 1<thinsp>: <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method 1<thinsp>: <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Hydroxyisoleucine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonella Foenum-graecum Seed Powdered Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonelline Hydrochloride RS | Anton Bzhelyansky |

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| New | FENUGREEK SEED POWDER PF 39(6) Pg. ONLINE | Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography-Amino Acid Profile, IDENTIFICATION/B. Thin-Layer Chromatography-Steroidal Saponins Profile, COMPOSITION/Content of 4-Hydroxyisoleucine, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Presence of Trigonelline, SPECIFIC TESTS/Botanical Characteristics, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 1 <561>, SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives, Method 1 <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Hydroxyisoleucine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonella Foenum-graecum Seed Powdered Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonelline Hydrochloride RS | Anton Bzhelyansky |
| New | FENUGREEK SEED POWDERED EXTRACT PF 39(6) Pg. ONLINE | Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatography-Amino Acid Profile, IDENTIFICATION/B. Thin-Layer Chromatography-Steroidal Saponins Profile, COMPOSITION/Content of 4-Hydroxyisoleucine, CONTAMINANTS/Elemental Impurities-Procedures <233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Presence of Trigonelline, SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Residue on Ignition <281>, SPECIFIC TESTS/Residual Solvents <565>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Hydroxyisoleucine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonella Foenum-graecum Seed Powdered Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Trigonelline Hydrochloride RS | Anton Bzhelyansky |
| Revision | FLUOROMETHOLONE PF 40(1) Pg. ONLINE | IDENTIFICATION/Ultraviolet Absorption <197U>, IDENTIFICATION/C. Thin Layer Chromatography, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluorometholone Related Compound A RS | Domenick Vicchio |
| Revision | FLUOROMETHOLONE OPHTHALMIC SUSPENSION PF 40(1) Pg. ONLINE | IDENTIFICATION/A. Thin-Layer Chromatography, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Fluorometholone Related Compound A RS | Domenick Vicchio |
| New | G##_Octreotide Acetate, PTA-5 PF 36(6) Pg. 1778 | G## (Octreotide Acetate, PTA-5) | Chensheng Li |
| Revision | GENTAMICIN AND PREDNISOLONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | IDENTIFICATION/A. Thin-Layer Chromatography, ASSAY/Prednisolone Acetate, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other | Ahalya Wise |

Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage

IDENTIFICATION/A. Thin-Layer Chromatography, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage

Revision GENTAMICIN SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE

[Ahalya Wise](#)

Title, Chemical Info/Chemical Structure, Chemical Info/C11H22O4, Chemical Info/218.29, Chemical Info/Octanoic acid, monoester with 1,2,3-propanetriol;, Chemical Info/Caprylic acid monoglyceride;, Chemical Info/Glyceryl mono-octanoate;, Chemical Info/Monocapryl glyceride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acid Composition, IDENTIFICATION/B. Glyceride Content, IDENTIFICATION/C. Fats and Fixed Oils, Saponification Value <401>, ASSAY/Contents of Monoglycerides, Diglycerides, and Triglycerides, IMPURITIES/Total Ash, IMPURITIES/Limit of Free Glycerol, SPECIFIC TESTS/Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glyceryl Monocaprylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caprate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caproate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caprylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Laurate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Myristate RS

New GLYCERYL MONOCAPRYLATE PF 40(3) Pg. ONLINE

[Hong Wang](#)

Title, Chemical Info/Chemical Structure, Chemical Info/C11H22O4, Chemical Info/ C13H26O4, Chemical Info/Octanoic acid, monoester with 1,2,3-propanetriol and decanoic acid, monoester with 1,2,3-propanetriol;, Chemical Info/Caprylic acid monoglyceride and capric acid monoglyceride;, Chemical Info/Glyceryl mono-octanoate and glyceryl monodecanoate., DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acid Composition, IDENTIFICATION/B. Glyceride Content, IDENTIFICATION/C. Fats and Fixed Oils, Saponification Value <401>, ASSAY/Contents of Monoglycerides, Diglycerides, and Triglycerides, IMPURITIES/Total Ash, IMPURITIES/Limit of Free Glycerol, SPECIFIC TESTS/ Fats and Fixed Oils, Acid Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Water Determination, Method Ia <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glyceryl Monocaprylocaprate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caprate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caproate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Caprylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Laurate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Myristate RS

New GLYCERYL MONOCAPRYLOCAPRATE PF 40(3) Pg. ONLINE

[Hong Wang](#)

IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Isoleucine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Leucine RS

Revision GLYCINE PF 40(3) Pg. ONLINE

[Huy Dinh](#)

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| Revision | GONADORELIN ACETATE PF 40(3) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, OTHER COMPONENTS/Acetic Acid in Peptides <503>, IMPURITIES/Gonadorelin Related Impurities, IMPURITIES/Acetic Acid and, IMPURITIES/Limit of Fluoride, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Bacterial Endotoxins <85>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>, SPECIFIC TESTS/Amino Acid Analysis, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Glacial Acetic Acid RS | Chensheng Li |
| Revision | HALOBETASOL PROPIONATE PF 40(2) Pg. ONLINE | ASSAY/Procedure, IMPURITIES/Organic Impurities | Hillary Cai |
| Revision | HYDROCODONE BITARTRATE PF 39(3) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Water Determination <921>, Method I, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Dihydrocodeine Bitartrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrocodone RS | Hillary Cai |
| Revision | HYDROCORTISONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | SPECIFIC TESTS/Particulate Matter, SPECIFIC TESTS/Other Requirements, SPECIFIC TESTS/Minimum Fill <755> | Domenick Vicchio |
| Revision | IDOXURIDINE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Shankari Shivaprasad |
| New | IFOSFAMIDE INJECTION PF 40(3) Pg. ONLINE | Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of 2-Chloroethylamine, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Color and Light Transmission, SPECIFIC TESTS/Osmolality and Osmolarity, Osmolality <785>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ifosfamide RS | Feiwen Mao |
| New | IMATINIB MESYLATE PF 39(6) Pg. ONLINE | Title, Chemical Info/Chemical Structure, Chemical Info/C29H31N7O.CH4O3S, Chemical Info/589.71, Chemical Info/C29H31N7O, Chemical Info/493.60, Chemical Info/Benzamide, 4-[(4-methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]aminophenyl]-, methanesulfonate salt; , Chemical Info/N-(4-Methyl-3-{[4-(pyridin-3-yl)pyrimidin-2-yl]amino}phenyl)-4-[(4-methylpiperazin-1-yl)methyl]benzamide mesylate, Chemical Info/CAS, Chemical Info/Imatinib, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197M>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Isopentyl Methanesulfonate, IMPURITIES/Limit of Imatinib Related Compound F, IMPURITIES/Limit of 1-Methylpiperazine, IMPURITIES/Limit of 3-Acetylpyridine, IMPURITIES/Limit of Dimethylamine, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 3-Acetylpyridine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cyclizine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards | Feiwen Mao |

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| | | <11>/USP Dimethylamine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib Mesylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib System Suitability Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Isopentyl Methanesulfonate RS | |
| New | IMATINIB TABLETS PF 39(6) Pg. ONLINE | Title, DEFINITION/Introduction, IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Imatinib Related Compound F, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib Mesylate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Imatinib System Suitability Mixture RS | Feiwen Mao |
| New | L##_Polyethylene Glycol 3350, Aquagel OH 40 PF 40(1) Pg. ONLINE | L##_ (Polyethylene Glycol 3350, Aquagel-OH40) | Hong Wang |
| New | L##_Polyethylene Glycol 3350, TSKgel G-Oligo-PW PF 40(1) Pg. ONLINE | L##_ (Polyethylene Glycol 3350, TSKgel G-Oligo-PW) | Hong Wang |
| Revision | L85 PF 39(3) Pg. ONLINE | L##_ (Adenine, GC <227>, Acclaim Mixed-Mode WCX-1) | Clydewyn Anthony |
| New | L86 PF 40(2) Pg. ONLINE | L86 | Margareth Marques |
| Revision | L87 PF 36(6) Pg. 1779 | L##_ (Octreotide Acetate, Synergi Max-RP) | Chensheng Li |
| New | LEVOCETIRIZINE DIHYDROCHLORIDE TABLETS PF 40(2) Pg. ONLINE | Title, DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorobenzhydryl Piperazine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Levocetirizine Dihydrochloride RS | Mary Koleck |
| New | (R)-(+)-LIMONENE PF 39(4) Pg. ONLINE | Reagent Specification, (R)-(+)-Limonene | Hong Wang |
| New | LINEZOLID PF 40(3) Pg. ONLINE | Chemical Info/Chemical Structure, Chemical Info/C16H20FN3O4, Chemical Info/337.35, Chemical Info/Acetamide, N-[[3-[3-fluoro-4-(4-morpholinyl)phenyl]-2-oxo-5-oxazolidinyl]methyl]-, (S)-;-, Chemical Info/N-[[3-(3-Fluoro-4-morpholinophenyl)-2-oxo-5-oxazolidinyl]methyl]acetamide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Enantiomeric Purity, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Linezolid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP | Ahalya Wise |

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| | | Linezolid R-isomer RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Linezolid Related Compound D RS | |
| Revision | LOPERAMIDE HYDROCHLORIDE TABLETS PF 40(2) Pg. ONLINE | IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Loperamide Related Compound F RS | Elena Gonikberg |
| Revision | MAGNESIUM SALICYLATE PF 40(1) Pg. ONLINE | C14H10MgO6, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicylic Acid Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicylic Acid Related Compound B RS | Hillary Cai |
| Revision | METHIMAZOLE PF 40(1) Pg. ONLINE | IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Ordinary Impurities <466>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methimazole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methimazole Related Compound C RS | Elena Gonikberg |
| Revision | METHYL SALICYLATE PF 40(2) Pg. ONLINE | IDENTIFICATION/B. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Limit of Salicylic Acid and Dimethyl 4-Hydroxyisophthalate, SPECIFIC TESTS/Refractive Index <831>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Salicylate Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicylic Acid RS | Galina Holloway |
| Revision | METHYLDOPA PF 39(2) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Limit of 3-O-Methylmethyldopa, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 3-O-Methylmethyldopa RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyldopa Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyldopa Related Compound C RS | Sujatha Ramakrishna |
| New | 1-MONODECANOYL-RAC-GLYCEROL PF 40(3) Pg. ONLINE | 1-Monodecanoyl-rac-glycerol | Hong Wang |
| New | 1-MONOCTANOYL-RAC-GLYCEROL PF 40(3) Pg. ONLINE | 1-Monooctanoyl-rac-glycerol | Hong Wang |
| Revision | MYRISTYL ALCOHOL PF 40(1) Pg. ONLINE | Title, Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Related Fatty Alcohols, SPECIFIC TESTS/Melting Range or Temperature, Class II <741>, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lauryl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Stearyl Alcohol RS | Galina Holloway |

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| Revision | NEOMYCIN SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Revision | NEOMYCIN SULFATE AND DEXAMETHASONE SODIUM PHOSPHATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | ASSAY/Dexamethasone Phosphate, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Revision | NEOMYCIN AND POLYMYXIN B SULFATES OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Revision | NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Revision | NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN, AND HYDROCORTISONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | ASSAY/Hydrocortisone Acetate, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Revision | NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage | Ahalya Wise |
| Revision | NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN ZINC, AND HYDROCORTISONE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | ASSAY/Hydrocortisone, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Revision | NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN ZINC, AND HYDROCORTISONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | ASSAY/Hydrocortisone Acetate, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage | Ahalya Wise |
| Revision | NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | ASSAY/Dexamethasone, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method Ib <921>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Revision | NICOTINE PF 40(2) Pg. ONLINE | IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nicotine Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nicotine Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nicotine Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nicotine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nicotine Related Compound E RS, | Ravi Ravichandran |

ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP
Nicotine Related Compound F RS, ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>/USP Nicotine Related Compound G RS

Chemical Info/Chemical Name[(C4H6O2)x(C10H10)y](C10H14N2) 2-
Propenoic acid, 2-methyl-, polymer with diethenylbenzene, complex with
(S)-3-(1-methyl-2-pyrrolidinyl)pyridine; Methacrylic acid polymer with
divinylbenzene, complex with nicotine 96055-45-7 Chemical Info/CAS,
IDENTIFICATION/B. Infrared Absorption <197K>, IDENTIFICATION/C.,
ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC
TESTS/Nicotine Release, ADDITIONAL REQUIREMENTS/USP Reference
Standards <11>/USP Nicotine Related Compound A RS, ADDITIONAL
REQUIREMENTS/USP Reference Standards <11>/USP Nicotine Related
Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards
<11>/USP Nicotine Related Compound C RS, ADDITIONAL
REQUIREMENTS/USP Reference Standards <11>/USP Nicotine Related
Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards
<11>/USP Nicotine Related Compound E RS, ADDITIONAL
REQUIREMENTS/USP Reference Standards <11>/USP Nicotine Related
Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards
<11>/USP Nicotine Related Compound G RS

[Ravi
Ravichandran](#)

Revision NICOTINE POLACRILEX PF 40(2) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. Botanic
Characteristics, IDENTIFICATION/B. Thin-Layer Chromatography,
IDENTIFICATION/C. HPLC, COMPOSITION/Content of Lignans,
CONTAMINANTS/Elemental Impurities-Procedures <233>,
CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide
Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests
<2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>,
CONTAMINANTS/Articles of Botanical Origin, Aflatoxins <561>, SPECIFIC
TESTS/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying <731>,
SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC
TESTS/Articles of Botanical Origin, Water-Soluble Extractives <561>,
SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives
<561>, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic
Matter <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage,
ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>/USP Schisandra chinensis Fruit Dry Extract RS,
ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP
Schisandrins RS

[Christopher
Okunji](#)

New NORTHERN SCHISANDRA FRUIT PF 40(2) Pg. ONLINE

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer
Chromatography, IDENTIFICATION/B. HPLC, COMPOSITION/Content of
Lignans, CONTAMINANTS/Elemental Impurities-Procedures <233>,
CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide
Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests
<2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>,
CONTAMINANTS/Articles of Botanical Origin, Test for Aflatoxins <561>,
SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying
<731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>,
SPECIFIC TESTS/Articles of Botanical Origin, Water-Soluble Extractives
<561>, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble
Extractives <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage,
ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP

[Christopher
Okunji](#)

New NORTHERN SCHISANDRA FRUIT POWDER PF 40(2) Pg. ONLINE

Reference Standards <11>/USP Schisandra chinensis Fruit Dry Extract RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Schisandrin RS

New OCTANESULFONIC ACID SODIUM SALT, MONOHYDRATE PF 39(6) Pg. ONLINE

Octanesulfonic Acid Sodium Salt, Monohydrate

[Feiwen Mao](#)

Title, Chemical Info/Chemical Structure, Chemical Info/C49H66N10O10S2·xC2H4O2, Chemical Info/l-Cysteinamide, d-phenylalanyl-l-cysteinyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl-N-[2-hydroxy-1-(hydroxymethyl)propyl]-, cyclic (2→7)-disulfide, [R-(R*,R*)]-, acetate (salt);, Chemical Info/d-Phenylalanyl-l-cysteinyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)propyl]-l-cysteinamide cyclic (2→7)-disulfide acetate (salt);, Chemical Info/d-Phenylalanyl-l-hemicystyl-l-phenylalanyl-d-tryptophyl-l-lysyl-l-threonyl-l-hemicystyl-l-threoninol cyclic (2→7)-disulfide acetate (salt)., Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1: Limit of Octreotide Acetate Related Compounds, IMPURITIES/Organic Impurities/Procedure 2: Limit of Trifluoroacetic acid (TFA), IMPURITIES/Organic Impurities/Procedure 3: Limit of Triethylamine, SPECIFIC TESTS/Amino acid content, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Acetic Acid Content <503>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Bacterial Endotoxins <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Octreotide Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Octreotide Acetate (Non-Cyclic) System Suitability Marker RS, ADDITIONAL REQUIREMENTS/USP Reference standards <11>/USP Glacial Acetic Acid RS

New OCTREOTIDE ACETATE PF 36(6) Pg. 1559

[Chensheng Li](#)

Chemical Info, DEFINITION/Introduction, IDENTIFICATION/A. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Related Fatty Alcohols, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Saponification Value <401>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Capric Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cetyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Linoleyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleyl Alcohol RS

Revision OCTYLDODECANOL PF 40(2) Pg. ONLINE

[Galina Holloway](#)

DEFINITION/Introduction, IDENTIFICATION/A. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Related Fatty Alcohols, SPECIFIC TESTS/Cloud Point, SPECIFIC TESTS/Refractive Index <831>, SPECIFIC TESTS/Fats and Fixed Oils, Iodine Value <401>, SPECIFIC TESTS/Fats and Fixed Oils, Peroxide Value <401>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

Revision OLEYL ALCOHOL PF 40(2) Pg. ONLINE

[Galina Holloway](#)

Revision BLAND LUBRICATING OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE

SPECIFIC TESTS/Homogeneity, SPECIFIC TESTS/Metal Particles in

[Feiwen Mao](#)

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|----------|---|--|-----------------------------------|
| | | Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | |
| Revision | OXYMETAZOLINE HYDROCHLORIDE PF 40(2) Pg. ONLINE | IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oxymetazoline Related Compound A RS | Feiwen Mao |
| Revision | OXYTETRACYCLINE HYDROCHLORIDE AND POLYMYXIN B SULFATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage | Ahalya Wise |
| New | 1-PENTADECANOL PF 40(2) Pg. ONLINE | 1-Pentadecanol | Margareth Marques |
| Revision | Pepsin PF 38(3) Pg. ONLINE | Pepsin | Margareth Marques |
| Revision | Pepsin, Purified PF 38(3) Pg. ONLINE | Reagent Specification, Pepsin, Purified | Margareth Marques |
| Revision | PHENYLEPHRINE BITARTRATE PF 40(2) Pg. ONLINE | Chemical Info/Chemical Name Benzenemethanol, 3-hydroxy-α- [(methylamino)methyl]-, (2R,3R)-2,3-dihydroxybutanedioate (1:1) (salt); (R)-(-)-m-Hydroxy-α-[(methylamino)methyl]benzyl alcohol hydrogen tartrate, DEFINITION/Introduction, IDENTIFICATION/B. Identification Tests-General, Tartrate <191>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Optical Rotation <781S>, Specific Rotation, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norphenylephrine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylephrine Bitartrate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylephrine Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylephrine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylephrine Related Compound E RS | Hillary Cai |
| Revision | PHENYLEPHRINE HYDROCHLORIDE PF 40(2) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Procedure, OTHER COMPONENTS/Content of Chloride, IMPURITIES/Limit of Ketones, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Norphenylephrine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylephrine Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylephrine Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenylephrine Related Compound E RS | Hillary Cai |
| Revision | PHENYTOIN PF 40(1) Pg. ONLINE | IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Limit of benzophenone, SPECIFIC TESTS/Clarity and Color of Solution, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzophenone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenytoin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenytoin Related Compound B RS | Ravi Ravichandran |

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|----------|---|---|-------------------------------------|
| New | POLYETHYLENE GLYCOL STANDARDS WITH MOLECULAR WEIGHTS OF 960, 1960, 3020, 6430, AND 12,300 DALTONS (G/MOL) PF 40(1) Pg. ONLINE | Polyethylene Glycol Standards with Molecular Weights of 960, 1960, 3020, 6430, and 12,300 Daltons (g/mol) | Hong Wang |
| Revision | POLYETHYLENE GLYCOL PF 39(6) Pg. ONLINE | SPECIFIC TESTS/Viscosity-Capillary Viscometer Methods <911> | Jenny Liu |
| New | POLYETHYLENE GLYCOL 3350 PF 39(6) Pg. ONLINE | Title, Chemical Info/Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-; , Chemical Info/1,2-Ethandiol, homopolymer, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals <231>, IMPURITIES/Limit of Ethylene Oxide and Dioxane, IMPURITIES/Limit of Ethylene Glycol and Diethylene Glycol, IMPURITIES/Limit of Formaldehyde and Acetaldehyde, SPECIFIC TESTS/Apparent Weight-Average Molecular Weight and Polydispersity, SPECIFIC TESTS/Acidity and Alkalinity, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Diethylene Glycol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ethylene Glycol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Polyethylene Glycol 3350 RS | Hong Wang |
| New | PROPAFENONE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES PF 40(3) Pg. ONLINE | Title, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, IMPURITIES/Content of Propafenone Related Compound A, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propafenone Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propafenone Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Propafenone Related Compound B RS | Sujatha Ramakrishna |
| Revision | PYRIDOSTIGMINE BROMIDE TABLETS PF 39(6) Pg. ONLINE | IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Pyridostigmine Related Compound A RS | Ravi Ravichandran |
| New | ROSUVASTATIN CALCIUM PF 40(2) Pg. ONLINE | Title, Chemical Info/Chemical Structure, Chemical Info/(C22H27FN3O6S)2 · Ca, Chemical Info/1001.14, Chemical Info/6-Heptenoic acid, 7-[4-(4-fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulfonyl)amino]-5-pyrimidinyl]-3,5-dihydroxy-, calcium salt (2:1), (3R, 5S, 6E); , Chemical Info/[S-[R*, S*-(E)]]-7-[4-(4-Fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulfonyl)amino]-5-pyrimidinyl]-3,5-dihydroxy-6-heptenoic acid, calcium salt (2:1); , Chemical Info/Calcium (3R,5S,E)-7-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)-3,5-dihydroxyhept-6-enoate salt (2:1), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests-General, Calcium <191>, ASSAY/Procedure, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, IMPURITIES/Limit of Chloride, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Calcium RS, ADDITIONAL | Sujatha Ramakrishna |

REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Rosuvastatin Related Compound D RS

New SABINENE PF 39(4) Pg. ONLINE

Reagent Specification, Sabinene

[Hong Wang](#)

Revision SODIUM CHLORIDE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE

ASSAY/Procedure, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage

[Mary Koleck](#)

Revision SODIUM SALICYLATE PF 40(3) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/B. Identification Tests-General, Salicylate and Sodium <191>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phenol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicylic Acid Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Salicylic Acid Related Compound B RS

[Hillary Cai](#)

New SPIRULINA PF 37(6) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Fatty Acids Profile, IDENTIFICATION/C. HPLC for Chlorophyll A, IDENTIFICATION/D. HPLC for Carotenoids, COMPOSITION/Content of Beta Carotene and Total Carotenoids, COMPOSITION/Content of C-Phycocyanin, COMPOSITION/Content of Protein, CONTAMINANTS/Limit of Microcystins, CONTAMINANTS/Elemental Contaminants, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Description, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linolenate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS

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New SPIRULINA TABLETS PF 37(6) Pg. ONLINE

DEFINITION/Introduction, IDENTIFICATION/A. Fatty Acids Profile, IDENTIFICATION/B. HPLC for Chlorophyll A, IDENTIFICATION/C. HPLC for Carotenoids, STRENGTH/Content of Beta Carotene and Total Carotenoids, STRENGTH/Content of C-Phycocyanin, STRENGTH/Content of Protein, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Limit of Microcystins, CONTAMINANTS/Elemental Contaminants <2233>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL

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| | | <p>REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Linolenate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Oleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Palmitoleate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Methyl Stearate RS</p> <p>Chemical Info/C18H38O, Chemical Info/270.49, DEFINITION/Introduction, IDENTIFICATION/A. Chromatographic Identity, ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Limit of Related Fatty Alcohols, SPECIFIC TESTS/Melting Range or Temperature <741>, SPECIFIC TESTS/Fats and Fixed Oils, Hydroxyl Value <401>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Arachidyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lauryl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Linolenyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Myristyl Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Oleyl Alcohol RS</p> | |
| Revision | STEARYL ALCOHOL PF 40(2) Pg. ONLINE | | <p>Galina Holloway</p> |
| Revision | SULFACETAMIDE SODIUM OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | <p>Shankari Shivaprasad</p> |
| Revision | SULFACETAMIDE SODIUM AND PREDNISOLONE ACETATE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | IDENTIFICATION/A., IDENTIFICATION/B., ASSAY/Sulfacetamide Sodium, ASSAY/Prednisolone Acetate, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | <p>Hillary Cai</p> |
| Revision | SULFAMETHOXAZOLE PF 39(6) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfamethoxazole Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfamethoxazole Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfamethoxazole Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfamethoxazole Related Compound F RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfanilic Acid RS | <p>Shankari Shivaprasad</p> |
| Revision | SULFAMETHOXAZOLE AND TRIMETHOPRIM TABLETS PF 40(3) Pg. ONLINE | IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulfamethoxazole Related Compound A RS | <p>Shankari Shivaprasad</p> |
| Revision | SULINDAC PF 40(1) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulindac Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sulindac Related Compound B, ADDITIONAL REQUIREMENTS/USP | <p>Hillary Cai</p> |

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| | | Reference Standards <11>/USP Sulindac Related Compound C | |
| Revision | TETRACYCLINE | IDENTIFICATION/C., IDENTIFICATION/D., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anhydrotetracycline Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epitetracycline Hydrochloride RS | Ahalya Wise |
| Revision | TETRACYCLINE HYDROCHLORIDE PF 40(2) Pg. ONLINE | IDENTIFICATION/D. Procedure, IDENTIFICATION/E., IDENTIFICATION/F., ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anhydrotetracycline Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epitetracycline Hydrochloride RS | Ahalya Wise |
| Revision | TETRACYCLINE HYDROCHLORIDE CAPSULES PF 40(3) Pg. ONLINE | ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Anhydrotetracycline Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Epitetracycline Hydrochloride RS | Ahalya Wise |
| Revision | TETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | IDENTIFICATION/A., PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP 4-Epianhydrotetracycline Hydrochloride RS | Ahalya Wise |
| Revision | TIMOLOL MALEATE PF 40(2) Pg. ONLINE | DEFINITION/Introduction, IDENTIFICATION/C., ASSAY/Titrimetry <541>, ASSAY/Procedure, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Timolol Related Compound B RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Timolol Related Compound C RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Timolol Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Timolol Related Compound E RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Timolol Related Compound F RS | Sujatha Ramakrishna |
| Revision | TOBRAMYCIN OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | IDENTIFICATION/A. Thin-Layer Chromatography, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| Revision | TOBRAMYCIN AND DEXAMETHASONE OPHTHALMIC OINTMENT PF 39(5) Pg. ONLINE | IDENTIFICATION/A. Thin-Layer Chromatography, PERFORMANCE TESTS/Minimum Fill <755>, SPECIFIC TESTS/Metal Particles in Ophthalmic Ointments <751>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Other Requirements | Ahalya Wise |
| New | TOLTERODINE TARTRATE PF 40(2) Pg. ONLINE | Chemical Info/Chemical Structure, Chemical Info/C22H31NO·C4H6O6, Chemical Info/475.57, Chemical Info/(R)-2-[3-[Bis(1-methylethyl)amino]-1-phenylpropyl]-4-methylphenol (2R,3R)-2,3-dihydroxybutanedioate (1:1) (salt);, Chemical Info/(+)-(R)-2-[α-[2-(Diisopropylamino)ethyl]benzyl]-p-cresol l-tartrate (1:1) (salt);, Chemical | Elena Gonikberg |

Info/(R)-2-[3-(Diisopropylamino)-1-phenylpropyl]-4-methylphenol tartrate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric Purity, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tolterodine S-Enantiomer RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tolterodine System Suitability Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tolterodine Tartrate RS

Chemical Info/Chemical Structure, Chemical Info/C23H23N3O5·HCl, Chemical Info/457.91 (n = 1), Chemical Info/1H-Pyrano[3′;4′:6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione, 10-[(dimethylamino)methyl]-4-ethyl-4,9-dihydroxy-, monohydrochloride, (S)-; , Chemical Info/(S)-10-[(Dimethylamino)methyl]-4-ethyl-4,9-dihydroxy-1H-pyrano[3′;4′:6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione monohydrochloride; , Chemical Info/CAS, Chemical Info/5/4 Hydrochloride, Chemical Info/C23H23N3O5·5/4 HCl, Chemical Info/467.02 (n = 5/4), Chemical Info/Topotecan, Chemical Info/C23H23N3O5, Chemical Info/421.45, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C., ASSAY/Procedure, OTHER COMPONENTS/Content of Chloride, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities, IMPURITIES/Limit of Methanol and Acetone (if it is present in the manufacturing process), IMPURITIES/Limit of Triethylamine (if it is present in the manufacturing process), SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topotecan Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topotecan Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Triethylamine RS

DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Particulate Matter in Injections <788>, SPECIFIC TESTS/Constituted Solution, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Irinotecan Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topotecan Hydrochloride RS

{Emulsifying Agent} Glyceryl Monocaprylate, {Emulsifying Agent} Glyceryl Monocaprylocaprate, {Lubricant} Glyceryl Monocaprylate, {Lubricant} Glyceryl Monocaprylocaprate, {Flavors and Perfumes} Eucalyptus Oil, {Coating Agent} Polyethylene Glycol 3350, {Diluent} Polyethylene Glycol 3350, {Film-Forming Agent} Polyethylene Glycol 3350, {Lubricant}

New TOPOTECAN HYDROCHLORIDE PF 39(1) Pg. ONLINE

[Feiwen Mao](#)

New TOPOTECAN FOR INJECTION PF 39(1) Pg. ONLINE

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Revision USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 40(3) Pg. ONLINE

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Polyethylene Glycol 3350, {Ointment Base} Polyethylene Glycol 3350, {Plasticizer} Polyethylene Glycol 3350, {Solvent} Polyethylene Glycol 3350, {Suppository Base} Polyethylene Glycol 3350

IMPURITIES/Related Compounds, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Alanine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Isoleucine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP I-Leucine RS

Revision VALINE PF 40(2) Pg. ONLINE

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